Commentary

FDA's Proposed Ban on Trans Fats: How Do the Costs and Benefits Stack Up?

Joshua T. Cohen, PhD

Center for the Evaluation of Value and Risk in Health and the Institute for Clinical Research and Health Policy Studies at Tufts Medical Center, Boston, Massachusetts

ABSTRACT

Objective: The goal of this commentary was to compare the benefits and costs of the US Food and Drug Administration's proposed ban on artificial trans fats in US food versus other public health risks and interventions.

Methods: This analysis assessed the remaining risk posed by artificial trans fats versus other risks, comparing them in terms of: (1) population disease burden (prevention of lost life-years and decreased quality of life, aggregated and expressed as quality-adjusted life-years [QALYs]); (2) individual mortality risks for other "voluntary" activities; and (3) cost-effectiveness, which is the unit cost incurred by an intervention per QALY gained.

Results: The population impact of remaining trans fats is small compared with many other risks. Conversely, lifetime individual risks are comparable to other individual risks that might be considered notable. Finally, the ban achieves public health gains at low to no cost.

Conclusions: The US Food and Drug Administration's ban on trans fats is sensible from the perspective of economic efficiency. Comparing the health risk addressed and the efficiency of the ban with other benchmarks can help decision makers and the population to better evaluate it. (*Clin Ther*. 2014;36:322–327)

Key words: cost-effectiveness, risk comparison, risk communication, trans fat.

INTRODUCTION

In November, the US Food and Drug Administration (FDA) proposed to effectively ban partially hydrogenated oils, the major contributor of artificial trans fats to the diets of Americans. The new rules would build on labeling requirements originally implemented in 2006. The FDA has credited those labeling requirements with prompting the reformulation of food products and an attendant 75% reduction in the original intake of artificially added trans fats by Americans from an average of 4.6 to 1.3 g/person-day.[1] FDA economist Richard Bruns estimated that this reduction already prevents 8000 to 18,000 coronary-related deaths annually[2] and that eliminating the remaining artificial trans fats from the US food supply would prevent an additional 3000 to 7000 deaths. Risks for individuals vary due to intake differences. The FDA estimated that intake for the 90th percentile individual is approximately twice the population mean.[1]

Preventing this many coronary events each year is noteworthy, especially because it has been accomplished with voluntary product reformulations, limited regulation, and little objection by the public. The fact that many products still contain trans fats, however, suggests that purging the trans fats which remain in the food supply will be more difficult.[2] Indeed, despite the health benefits, a recent Pew Research Center survey found that the majority of Americans oppose a ban on the use of trans fats in restaurants.[3] The goal of the present commentary was to shed light on the desirability of the FDA's proposed

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ban by comparing its costs and benefits with a range of benchmarks, including other health risks and the gains achieved by other public health interventions.

METHODS

This analysis assessed the remaining risk posed by artificial trans fats versus other risks, comparing them in terms of the following: (1) population disease burden (prevention of lost life-years and decreased quality of life); (2) individual mortality risks for other "voluntary" activities; and (3) cost-effectiveness, which is the unit cost incurred by an intervention per unit of health benefits accrued.

RESULTS

Population Disease Burden

In addition to the 3000 to 7000 coronary-related deaths caused annually, the Centers for Disease Control and Prevention estimate that the remaining trans fats in US diets are responsible for 10,000 to 20,000 coronary events each year.[4] These fatal and nonfatal effects can be aggregated and compared with the aggregate effects of other diseases by estimating losses in terms of lost quality-adjusted life-years (QALYs). Multiplication of life-years lived with an adverse health condition by a "quality weight" of <1.0 quantitatively captures the impact of that condition. The more severe the adverse condition, the smaller the weight, with conditions equally preferable to death assigned a weight of zero. This approach admittedly makes numerous assumptions, but it has the advantage of combining fatal and nonfatal impacts in a single number and making possible comparison of events that take place at different ages.

Bruns[2] estimated that, on average, coronary events caused by consumption of trans fats take place 13 years before the affected individual would have otherwise died and hence cause the loss of 13 QALYs. Because he estimated that nonfatal events diminish the quality of life weight by 0.18, Bruns concluded that each nonfatal heart attack caused the loss of 0.18×13 QALYs or a total of 2.34 QALYs. Assuming 3000 fatal events and 10,000 nonfatal events each year, trans fats cause an annual loss of 62,000 QALYs. A total of 7000 fatal events and 20,000 nonfatal events corresponds to an annual loss of $\sim$138,000 QALYs.

How does a loss of 62,000 to 138,000 QALYs compare with losses caused by other health risks? The US Burden of Disease Collaborators[5] estimated losses for 291 health risks in terms of disability-adjusted life-years, a metric that for our purposes is closely related to QALYs. The results of that analysis indicate that remaining trans fats have an impact that is $\sim$0.1% of total annual QALY losses in the United States (81 million QALYs) and 1% as large as the leading single contributor (all ischemic heart disease, 7.2 million QALYs per year). Health losses imposing a burden comparable to the impact of trans fats include enterotoxigenic *Escherichia coli* infection (58,000 QALYs), meningitis (107,000 QALYs), cancer of the larynx (89,000 QALYs), cervical cancer (164,000 QALYs), multiple sclerosis (154,000 QALYs), and drowning (224,000 QALYs).

Individual Risk

The relevance of aggregate population risks comparisons is limited by the fact that they represent averages that can conceal substantial variation among members of the population. For example, because they represent half the population, the individual risk of cervical cancer for women is approximately twice as great as the threat implied by the 164,000 QALY loss quoted earlier. It is even greater among that subgroup of women who do not undergo regular cervical cancer screening examinations. Similarly, the risk of drowning is much greater for people who swim than it is for others.[6]

Cohen and Neumann[7] catalogued individual mortality risks associated with various occupations, modes of transportation, and recreational activities, providing estimates for the number of deaths per 100,000 person-years of participation. The Figure illustrates corresponding lifetime fatalities per 100,000 subjects who engage in these activities. To convert the annualized risks reported by Cohen and Neumann into lifetime fatalities, this analysis makes approximate assumptions about how long individuals participate in these activities during a lifetime. The assumed duration of relatively active participation for each activity (in years) appears parenthetically in each horizontal axis tag. For example, the analysis assumed that occupational risks are incurred over a 10-year period for the most physically demanding jobs (eg, logging) and over a 35-year period for office jobs.

Each panel in the Figure compares 1 set of activities with the lifetime fatality risk associated with trans fat consumption in the United States. The population